

REMARKS

Claims 32-43, 46, 47 and 49-62 are currently pending. Claims 32-39 and 49-62 have been withdrawn as being directed to a non-elected invention. Applicant respectfully reserves the right to file divisional applications directed to the non-elected subject matter. Claim 42 has been amended to depend properly from claim 41. Support for this amendment can be found in paragraphs [0027] and [0038] of the specification of the published application (U.S. 2005/0042267). No new matter has been added by this amendment.

I. Rejection Under 35 U.S.C. § 112

Reconsideration is requested of the rejection of claim 42 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as his invention. Specifically, claim 42 has been amended to properly depend from claim 41, and, as such, the limitation "said third patch" possesses proper antecedent basis. Accordingly, Applicant respectfully requests withdrawal of this rejection.

II. Rejections under 35 U.S.C. § 103(a)

Reconsideration is requested of the rejection of claims 40, 41, 43, 46 and 47 under 35 U.S.C. § 103(a) as being unpatentable over Westplate (U.S. 4,592,358) in view of either Kanios, et al. (U.S. 6,905,016) or Sudsina, et al. (U.S. 6,004,345).

Claim 40 is directed to a system for providing therapy to a portion of the body. The system comprises:

a container that includes at least one compartment;

a first patch held by said container, wherein said first patch applies a first therapy to the portion of the body when said first patch engages the portion of the body;

a second patch held by said container, wherein said second patch applies a second therapy to the portion of the body when said second patch engages the portion of the body, the second therapy being different than the first therapy; and

a flexible wrap held by said container, the flexible wrap being adapted to secure at least one of said first patch and said second patch to the portion of the body, wherein the first patch, the second patch and the flexible wrap are all within the same compartment in the container.

Westplate is directed to a therapeutic device featuring a plurality of compartments enclosing a therapeutic substance. The therapeutic substance can be a refrigerant material or a heat releasing substance. The therapeutic device may be encircled or conformed to a portion of the body. Further, packets of variable weights may be accommodated in the compartments of the therapeutic device in order to compress an injured area while simultaneously heating or cooling the area.

Significantly, however, as recognized by the Office on page 6 of the instant Office action, Westplate does not disclose or suggest placing the packets and the therapeutic device all within the same compartment in a container. Recognizing the deficiencies of Westplate, the Office cites either Kanios, et al. or Sudsina, et al. for combination with Westplate in an attempt to arrive at each and every limitation of Applicant's claim 40.

Kanios, et al. discloses a transdermal delivery system. The system includes a product packaging system to prevent or control degradation reactions that can result from certain packaging materials and moisture contamination while providing a child-resistant wrapping for the transdermal system. The packaging system includes a primary layer and a secondary layer held together by an adhesive material that form the pouch. The pouch can contain multiple packages of a transdermal drug. The transdermal drug can be methylphenidate.

Sudsina, et al. disclose a therapeutic wrap for sore throats. The therapeutic wrap can be placed in a kit with a vaporizing ointment. The wrap helps to keep the user's neck and chest warm so that the vaporizing ointment can have its maximum effect.

In order for the Office to show a *prima facie* case of obviousness, M.P.E.P. § 2142 requires a clear articulation of the reasons why the claimed invention would have been obvious. Specifically, to reject a claim based on this rationale, the Office must articulate the following: (1) a finding that there was some teaching, suggestion, or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings to arrive at each and every limitation of the claimed invention; (2) a finding that there was reasonable expectation of success; and (3) whatever additional findings based on the Graham factual inquiries may be necessary, in view of the facts of the case under consideration, to explain a conclusion of obviousness. The Office has failed

to meet its burden under number (1) above, as the cited references fail to show each and every limitation of Applicant's invention and there is no apparent reason for one skilled in the art to modify/combine the references to arrive at each and every limitation. It simply would not have been obvious to one skilled in the art to arrive at Applicant's claimed combinations.

Specifically, the combination of cited references fails to disclose or suggest a system comprising a first patch, a second patch and a flexible wrap all within the same compartment in a container, wherein the second patch and the first patch apply different therapies to the body, as is required in Applicant's claim 40. This is a significant aspect of Applicant's invention, as the system allows a user or therapist to conveniently apply one or more alternative therapies to an injured portion of a body (see, e.g., para. [0011] of the published application (U.S. 2005/0042267 A1)).

Instead, at best, the combination of cited references discloses placing a patch and/or packet, with a single therapy, in a container. In particular, as noted by the Office, Westplate discloses packets that provide more than one therapy (such as heating or cooling), however, the packets are individually placed in the compartments of Westplate, and are not placed in the compartments together, or, with a flexible wrap, as the flexible wrap in Westplate is the container. Similarly, though Kanios, et al. disclose a packaging system that can have multiple packets in one pouch, the packets all contain a single therapy. Further, though Sudsina, et al. disclose a vaporizing ointment in the same container as a

flexible wrap, again, the vaporizing ointment is a single therapy, and there is no disclosure in Sudsina, et al. of a flexible wrap in the same container with two different therapies, as is required in Applicant's claim 40. Thus, nowhere does either the combination of Westplate and Kanios, et al. or the combination of Westplate and Sudsina, et al. ever disclose a container that holds a flexible wrap and a first and second patch, wherein the first and second patch provide different therapies to a user of the system, within the same compartment. As such, the combination of cited references fails to provide a *prima facie* case of obviousness because the combination of cited references fails to disclose each and every limitation of Applicant's claim 40.

Moreover, even if the combination of cited references disclosed each and every element of Applicant's claim 40 (which, as noted above, Applicant respectfully submits that they do not), there is no apparent reason to modify/combine the cited references in order to arrive at each and every element of Applicant's claim 40.

On page 7 of the instant Office action, the Office argues that it would have been obvious to enclose the device of Westplate in a container as taught by Kanios, et al. because the patches of Westplate could be protected from moisture contamination and environmental factors. Applicant respectfully disagrees. Specifically, Westplate already provides for a means of protecting the packets disclosed therein. In particular, the packets disclosed therein are made up of a "double layer of durable, flexible, liquid impervious material."¹ As such, why

¹ Westplate, column 5, lines 9-11.

would one having ordinary skill in the art look to Kanios, et al. in order to have more protection from moisture contamination and environmental factors? It simply cannot be stated that it would be obvious to do so. With all due respect, it appears that the Office is using impermissible hindsight, using Applicant's invention as a blueprint, to arrive at such a combination. Given that nowhere does Westplate recognize or discuss the importance of having a flexible wrap and the packets having different therapies placed within the same container, and, given that there is no articulated reason to combine the Westplate and Kanios, et al. references in order to arrive at Applicant's claim 40, Applicant respectfully submits that claim 40 is patentable over the combination of Westplate and Kanios, et al.

Further, there is no articulated reason to combine Westplate with Sudsina, et al. to arrive at the specific system for providing therapy as disclosed in Applicant's claim 40. On page 7 of the instant Office action, the Office states that it would have been obvious to combine Westplate and Sudsina, et al. so that the packages and wrap could be conveniently stored together. As noted above, however, neither reference discloses or recognizes the importance of having two different therapies (as patches or packets) stored together with a flexible wrap within the same compartment in a container. Moreover, Sudsina, et al. does not even recognize a system that has more than one therapy. That is, Sudsina, et al. focus solely on a vaporizing ointment for a sore throat. As such, why would one having ordinary skill in the art, when looking to modify/combine a therapeutic device with multiple therapies, look to a reference that discloses a single therapy? It simply cannot be stated

that it would be obvious to do so. There is simply nothing in Westplate that discloses or recognizes a need for a "convenient" way to store the packages and the therapeutic device together and, even if there were such a recognition, one having ordinary skill in the art would not look to a reference such as Sudsina, et al., which does not disclose or recognize the importance of having different therapies and a flexible wrap stored together within the same compartment of a container. Again, it appears that the Office is using Applicant's disclosure as a blueprint to impermissibly pick and choose elements from the prior art in an attempt to arrive at the specific system of Applicant's claim 40. As noted above, such hindsight reconstruction and analysis is prohibited. Accordingly, Applicant submits that claim 40 is patentable over the combination of Westplate and Sudsina, et al.

For the reasons set forth above, the combination of cited references fails to disclose or suggest each and every element of Applicant's claim 40, and, further, there is no articulated reason to modify/combine the cited references in order to arrive at the specific system for providing therapy to a portion of a body as disclosed in Applicant's claim 40. Accordingly, claim 40 is patentable over the combination of cited references.

Claims 41, 43, 46 and 47 depend from claim 40 and are thus patentable over the combination of cited references for the same reasons set forth above with respect to claim 40, as well as for the additional elements they require.

III. Rejections under 35 U.S.C. § 103(a)

Reconsideration is requested of the rejection of claim 42 under 35 U.S.C. § 103(a) as being unpatentable over Westplate (U.S. 4,592,358) in view of either Kanios, et al. (U.S. 6,905,016) or Sudsina, et al. (U.S. 6,004,345) as applied to claims 40, 41, 43, 46 and 47 above, and further in view of Zhang, et al. (U.S. 6,245,347).

Claim 42 depends from claim 40, which is discussed above.

Westplate, Kanios, et al. and Sudsina, et al. are discussed above. As noted above, the combination of Westplate and Kanios, et al. and/or the combination of Westplate and Sudsina, et al. fail to disclose each and every element of Applicant's claim 40. Recognizing the deficiencies of the cited references, the Office cites Zhang, et al. in combination with the cited references in an attempt to arrive at each and every element of Applicant's claim 42.

Zhang, et al. disclose methods and an apparatus for improving administration of drugs through the use of heat and other physical means. The drugs can be delivered into a sub-skin depot site via injection and other methods to alter, mainly increase, the drug release rate from the dermal drug delivery systems or the depot sites to accommodate certain clinical needs.

Significantly, identical to the references cited above, Zhang, et al. fail to disclose or suggest a system wherein a first patch and a second patch that provide different therapies being held with a flexible wrap within the same compartment in a

container. As such, the combination of cited references fails to disclose each and every element of Applicant's claim 40.

Further, there is no articulated reason to modify/combine the cited references in order to arrive at the specific system for providing therapy to a portion of a body as required in Applicant's claim 40. On page 9 of the instant Office action, the Office states that it would have been obvious to combine the cited references because Westplate desired to treat injured parts of the body that may need analgesia. Applicant respectfully disagrees.

Specifically, as noted above, neither Westplate nor Zhang, et al. disclose a container that holds a flexible wrap and a first patch and a second patch with different therapies within the same compartment. In fact, if anything, Zhang, et al. actually teaches away from having the dermal drug delivery system in a compartment with a heating or cooling mechanism. That is, Zhang, et al. expressly teach that the temperature control apparatus and the dermal drug delivery system are preferably stored in separate compartments of the container.² As such, why would one having ordinary skill in the art look to place the temperature control apparatus and the dermal drug delivery system of Zhang, et al. within the same compartment? It simply cannot be stated that it would be obvious to do so. Accordingly, claim 40 is patentable over the combination of cited references.

Claim 42 depends from claim 40 and is thus patentable over the combination of cited references for the same reasons set

² Zhang, et al., column 12, lines 5-9.

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forth above with respect to claim 40, as well as for the additional limitations it requires.

CONCLUSION

For the reasons stated above, Applicant respectfully requests that the Examiner's rejections be reversed and that the pending claims be allowed. The Commissioner is hereby authorized to charge any fees which may be required to Deposit Account Number 01-2384.

Respectfully Submitted,

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